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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/052,417	01/17/2002	David Harrow Gelfand	1803-0329-999	4095

41504 7590 02/15/2006

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EXAMINER

SITTON, JEHANNE SOUAYA

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/052,417	Applicant(s) GELFAND ET AL.	
	Examiner Jehanne S. Sitton	Art Unit 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 25 November 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6-8, 11-13, 16-18, 21-23, 26-27, 31-36, 39-42, 45-47, and 50-52 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-3, 6-8, 11-13, 16-18, 21-23, 26-27, 31-36, 39-42, 45-47, and 50-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. Currently, claims 1-3, 6-8, 11-13, 16-18, 21-23, 26-27, 31-36, 39-42, 45-47, and 50-52 are pending in the instant application. Finality of the previous office action is withdrawn. The amendment filed 11/15/2005 has been entered. The following office action contains new grounds of rejection. Any rejection not reiterated from the previous office action is withdrawn in view of the amendments to the claims. The following rejections constitute the complete set being presently applied to the instantly pending claims. This action is NON-FINAL.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

New Grounds of Rejection

Claim Rejections - 35 USC § 102

3. Claims 1-3, 6-8, 11-13, 16-18, 21-23, 26-27, 31, 33-36, 39-42, and 45-47 are rejected under 35 USC 102(e) as being anticipated by Brandis I (Brandis et al; US Patent 6,265,193).

Brandis I teaches and claims mutant DNA polymerases having at least one mutation at position 681 with respect to Taq DNA polymerase, wherein the mutant DNA polymerase has at least 2 fold reduced discrimination against the incorporation of a fluorescein type dye labeled nucleotide as compared to a naturally occurring DNA polymerase (see claims 1-13, col. 6, lines 4-39, col. 8, Tables 1 and 2 at cols 17-22).

With regard to claims 1-3, 6-8, 33-36, 39-42, and 45-47, Brandis I teaches making the specific mutants in Taq polymerase, which comprises SEQ ID NOS 1-3, as acknowledged by the

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instant specification at page 15. Brandis I teaches making a number of mutants at position 681 of Taq, which have at least 3 fold lower discrimination (table 2, cols 21-22). Brandis teaches making the specific E681K mutant. Brandis I teaches kits comprising the mutant polymerase and a fluorescently labeled nucleotide dye (claims 6-9), fluorescein type dyes (col. 4), and nucleotides which are any naturally occurring nucleotides or analogs such as 2',3' dideoxynucleotides (chain terminator) (col. 4, lines 35-39).

With regard to claims 11-13 and 16-18, Brandis I teaches providing polynucleotides encoding the mutant polymerases (abstract, all of col. 11, especially lines 40-45).

With regard to claims 21-23, 26-27, and 31 Brandis I teaches to use the mutant polymerases in methods of Sanger sequencing such as dideoxy nucleotide chain termination, PCR, polynucleotide labeling, and minisequencing.

4. Claims 1-3, 6-8, 11-13, 16-18, 21-23, 26-27, 31, 33-36, 39-42, and 45-47 are rejected under 35 USC 102(e) as being anticipated by Brandis II (Brandis et al; US PreGrant Publication 2002/0164591).

Brandis II teaches and claims mutant DNA polymerases having at least one mutation at position 681 with respect to Taq DNA polymerase, wherein the mutant DNA polymerase has at least 2 fold reduced discrimination against the incorporation of a fluorescein type dye labeled nucleotide as compared to a naturally occurring DNA polymerase (see claims 1-8, 15, Tables 1 and 2).

With regard to claims 1-3, 6-8, 33-36, 39-42, and 45-47, Brandis II teaches making the specific mutants in Taq polymerase, which comprises SEQ ID NOS 1-3, as acknowledged by the

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instant specification at page 15. Brandis II teaches making a number of mutants at position 681 of Taq, which have at least 3 fold lower discrimination (table 2,). Brandis teaches making the specific E681K mutant. Brandis II teaches kits comprising the mutant polymerase and a fluorescently labeled nucleotide dye, fluorescein type dyes, and nucleotides which are any naturally occurring nucleotides or analogs such as 2',3' dideoxynucleotides (chain terminator).

With regard to claims 11-13 and 16-18, Brandis II teaches providing polynucleotides encoding the mutant polymerases (abstract, claim 9 of Brandis II)

With regard to claims 21-23, 26-27, and 31 Brandis II teaches to use the mutant polymerases in methods of Sanger sequencing such as dideoxy nucleotide chain termination, PCR, polynucleotide labeling, and minisequencing.

Claim Rejections - 35 USC § 103

5. Claims 32 and 50-52 are rejected under 35 USC 103(a) as being unpatentable over Brandis I or II, each in view of Gelfand (US Patent 5,939,292).

Brandis I and II teach mutant DNA polymerases having at least one mutation at position 681 with respect to Taq DNA polymerase, wherein the mutant DNA polymerase has at least 2 fold reduced discrimination against the incorporation of a fluorescein type dye labeled nucleotide as compared to a naturally occurring DNA polymerase. Brandis I and II teach making the specific E681K mutant. Brandis I and II teach kits comprising the mutant polymerase and a fluorescently labeled nucleotide dye, fluorescein type dyes, and nucleotides which are any naturally occurring nucleotides (encompasses dNTP and rNTP).

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With regard to claims 32 and 50-52, Brandis I and II teach to provide mutant polymerases comprising other mutations in addition to the discrimination mutations such as those at position 681 of Taq polymerase, including mutants outside the discrimination regions (col. 10, lines 9-23, Table 2, cols 19-22). Brandis I and II teach mutations at position 615 of Taq polymerase (instant SEQ ID NOS 18). Brandis I or II do not specifically teach a polymerase comprising *both* a mutation at position 681 and a mutation at position 615, however Gelfand teaches to use modified DNA polymerases with enhanced efficiency for incorporating unconventional nucleotides, such as ribonucleotides, using a polymerase with a mutation at position 615, corresponding to Taq polymerase, in methods of DNA sequencing (see abstract, cols 2-3). Therefore it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to provide a mutant DNA polymerase with both a mutation at position 681 and 615, relative to Taq, both taught by Brandis, in the mutant polymerases of Brandis I or II for use in the sequencing methods or primer extension (minisequencing) methods taught by Brandis I or II because Gelfand teaches that the mutation at position 615 in a DNA polymerase provides for DNA polymerases that enable alternative nucleic acid synthesis methods for accurate and cost effective nucleic acid DNA sequence analysis. It would have further been prima facie obvious to the ordinary artisan at the time the invention was made to provide such mutant polymerases and a ribonucleotide labeled with a fluorescein type family dye for the purposes of making the methods of Brandis I or II, each in view of Gelfand more convenient to perform.

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Conclusion

6. No claims are allowed.
7. It is noted that the filing of a declaration under 37 CFR 1.131 cannot be used to swear behind claims directed to subject which is claimed by the '193 patent. See MPEP 715 II:

An affidavit or declaration under 37 CFR 1.131 is not appropriate in the following situations:...

(B) Where the reference U.S. patent or U.S. patent application publication claims the same patentable invention. See MPEP § 715.05 for a discussion of "same patentable invention" and MPEP *> Chapter 2300<.

With regard to claims directed to subject matter claimed in a Publication for Patent, see MPEP 715.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday-Thursday from 8:00 AM to 5:00 PM and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (571) 272-0745. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

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history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Jehanne Sitton
Primary Examiner
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A handwritten signature in cursive script that reads "Jehanne Sitton".

2/3/06